

REMARKS

Claim 40 has been added as being directed to the elected species. Thus, claims 1-40 are pending in the present application.

1. Restriction Requirement

The Examiner has required a restriction in the present application between:

Group I, claims 1-30, drawn to a delivery system comprising a population of exopolysaccharide micelles, each said micelle defining a core for containing said active molecule;

Group II, claims 31-38, drawn to a method for delivering an active molecule to a patient. Please note that the “use” claims have been interpreted as a method of treating a patient; and

Group III, claim 39, drawn to a method for producing the delivery system.

Applicants respectfully traverse the Examiner’s restriction. The Examiner concedes in the Office Action that, the present claims fulfill the criteria for claims directed to multiple categories of inventions to be considered to have unity of invention. (See item 2 of the Office Action.) As clearly acknowledged by the Examiner, claims 1-30 are drawn to a delivery system, claims 31-38 are drawn to a method of using the delivery system; and claim 39 is drawn to a method of producing the delivery system. Thus, it is believed that the present claims are directed to a product, a process for manufacturing the product and to a process of use of said product, which are thus drawn to an acceptable combination (3) as disclosed on page 3 and 4 of the Office Action.

The Examiner cites Kachlany et al. as evidence that the claims do not encompass a common special technical feature. Applicants submit that Kachlany does not destroy novelty or non-obviousness. Kachlany does not teach a process for preparing exopolysaccharide micelles comprising the addition of deoxycholate. On the contrary, this reference is only directed to an analysis of exopolysaccharide capsule of *Pseudomonas putida* G7. This reference does not teach

a delivery system *per se*, even less a method of producing a delivery system. Thus, the claims pending in the present application are inventive over the cited art, thereby unifying the various group of invention together.

In addition, though the Examiner is theoretically using the PCT unity of invention criteria prescribed, no unity rejection issued during the PCT International Phase. According to *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F.Supp. 218, 231 USPQ 590 (E.D. Va. 1986), the USPTO is required to apply the 37 C.F.R. § 1.141(b)(2) (the restriction rule) in accordance with the Patent Cooperation Treaty and its implementing regulations. MPEP § 1850. Specifically, when examining national stage applications, “PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims . . . without regard to the practice in national applications filed under 35 U.S.C. 111.” *Id.* Consequently, Applicants submit that the Examiner is improperly applying Rule 13.1 of the PCT. Applicants therefore request that the Examiner withdraw the restriction.

Also, the Examiner’s statements are conclusory. The Examiner has not provided any more than conclusory statements suggesting that Kachlany “teaches a process for preparing exopolysaccharide micelles” as claimed in the instant invention. “A mere statement or conclusion is inadequate.” MPEP § 808.01. Accordingly, Applicants request that the Examiner withdraw the Restriction and the requirement of an election of species.

However, if the Examiner maintains the requirement then, **for the purpose of examination of the present application, Applicants elect, with traverse, Group I, Claims 1-30.**

2. Election of Species

The Examiner also imposes an election of species. Applicants submit that this species election is improper because there would be no serious burden on the Examiner to search the various species.

However, Applicants elect, with traverse, taxanes from claim 6. Claim 40 has been added as being directed to the elected species. It is believed that claims 1-6 and 30-40 are readable on the elected species.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Registration No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

- ☒ Attached is a Petition for Extension of Time.
- ☒ Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: July 29, 2009

Respectfully submitted,

By 

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